UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MITCHELL S. WORTZMAN, PHILIP J. GORDON, EUGENE H. GANS, and BHIKU G. PATEL

Appeal No. 2006-0230
Application No. 09/864,083

HEARD: March 7, 2006

Before ELLIS, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-23, which are all the claims pending in the application.

Claims 1, 2, 9, 11, 19, 21 and 23 are illustrative of the subject matter on appeal and are reproduced below:

1. A composition for the treatment of pigmentation disorders comprising: hydroquinone; and a cationic salt of acidic ascorbyl esters, said composition having a pH of about 5.5 to about 8.0.

2. The composition of claim 1 wherein the pH is about 5.5 to about 7.5.

9. The composition of claim 1 further comprising a water-soluble antioxidant.

11. The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite.

19. The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite and the cationic salt comprises magnesium ascorbyl phosphate.

21. The composition of claim 1 wherein the cationic salt comprises an amino acyl derivative.

23. The composition of claim 1 wherein the cationic salt comprises a sodium ascorbyl phosphate.

The references relied upon by the examiner are:

Gordon	5,932,612	Aug. 3, 1999
Lukenbach	5,980,871	Nov. 9, 1999

GROUNDS OF REJECTION

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Gordon.

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Lukenbach and Gordon.

We affirm the rejection of claims 1-10 and 14-18 under 35 U.S.C. § 103(a) as being obvious over Gordon. In addition, we affirm the rejection of claims 1-9 under 35 U.S.C. § 103(a) as being obvious over the combination of Lukenbach and Gordon. We reverse the rejection of claims 11-13 and 19-23 under 35 U.S.C. § 103(a) as being obvious over Gordon.

DISCUSSION

Gordon:

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Gordon.

The examiner finds (Answer, page 3), Gordon "teaches a skin lightening composition used in the treatment of hyperpigmentation, wherein said composition comprising a derivative of ascorbic acid such as magnesium ascorbyl phosphate, [and] hydroquinone." Specifically, Gordon teach (column 1, lines 44-51), compositions useful for treating and preventing hyperpigmentation that are "at least as effective as over the counter hydroquinone preparations, with dramatically reduced side effects." According to Gordon (column 1, lines 44 – column 2, line 5), the compositions comprise (1) tocopherol, or its dermally available derivatives (such as tocopherol acetate), (2) a derivative of ascorbic acid (such as ascorbityl palmitate, magnesium ascorbityl phosphate, and ascorbityl linoleate), and (3) a fatty acid (such as linolenic acid). In addition, Gordon teach (column 2, lines 66-67), the compositions may optionally include 1.5-4.0% hydroquinone. For clarity, we reproduce claims 1 and 2 of the Gordon patent below:

1. A composition for the treatment of hyperpigmentation, comprising:
   a) tocopherol or a dermally available derivative thereof,
   b) a dermally available derivative of ascorbic acid,
   c) a C_{12}-C_{20} fatty acid,
   d) a pharmaceutically acceptable carrier and
   e) hydroquinone.

2. The composition of claim 1, wherein the derivative of ascorbic acid is ascorbityl palmitate, ascorbityl linoleate, ascorbityl octanoate, or magnesium ascorbityl phosphate.

From the foregoing analysis it appears clear that Gordon teaches compositions for treating pigment disorders which comprise hydroquinone and a cationic salt of acidic ascorbyl esters. While appellants' composition, as claimed, comprises hydroquinone and a cationic salt of acidic ascorbyl esters, we note that claimed composition as exemplified in appellants' specification (paragraphs 32-35), contains tocopherol acetate and linoleic acid. Accordingly, as we understand it, appellants' specification discloses a composition comprising (1) tocopherol, or its dermally available derivatives (such as tocopherol acetate), (2) a derivative of ascorbic acid (such as ascorbityl palmitate, magnesium ascorbityl phosphate, and ascorbityl linoleate), (3) a fatty acid (such as linolenic acid) and hydroquinone. This is the composition taught, and claimed, by Gordon. See e.g., the formulations set forth in Table 1 (column 2) of Gordon, together with 1.5-4% hydroquinone as set forth on column 2, lines 66-67 as required by Gordon's claim 1.

Claim 1:

Appellants group claims 1 and 4-9 separately from claims 10 and 14-18. Brief, page 4[1]. Appellants, however, do not provide separate arguments for claims 10 and 14-18. Therefore, these claims will stand or fall together with the claims 1 and 4-9. Accordingly, we limit our discussion to representative claim 1. Claims 4-10 and 14-18 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

[1] The Brief is not paginated. Accordingly, for clarity, we refer to the Brief as if it was paginated consecutively starting with the first page.

Appellants focus our attention (Brief, pages 5-7), on the fact that Gordon does not address the pH of the compositions disclosed therein. In this regard, appellants argue that since Gordon does not teach a pH of about 5.5 to about 8.0, Gordon does not teach all the limitations of appellants' claimed invention and therefore cannot render appellants' claimed invention prima facie obvious. Id. However, as we understand the examiner's argument (Answer, page 4), compositions having similar ingredients would have a similar pH. Stated differently, given their similar ingredients, it would be reasonable to expect that the pH of Gordon's compositions would inherently be the same as, or within, the range set forth in appellants' claim. As set forth in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977), footnote omitted:

> Where, as here, the claimed and prior art products are identical or substantially identical, ... the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.... Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Apparently recognizing the burden placed on them by Best, appellants direct our attention to Exhibit 1 of the Brief which lists U.S. Patents 5,889,054 ('054), 5,962,526 ('526), and 5,554,652 ('652). Upon review of the three patents we note that the '652 patent is a continuation of United States Patent No. 5,470,880 ('880). The '054 and '526 patents are both a continuation of United States Patent 5,691,378, which in turn is a continuation of the '880 patent. Therefore, all three patents cited by appellants have the same disclosure.

Accordingly, we will address appellants' argument as it relates to the '054 patent. In this regard, appellants assert (Brief, page 7), the '054 patent teaches (column 7, lines 54-56, and column 13, lines 19-21), "compositions containing four percent (4%) or less hydroquinone are stably prepared in a pH range of 3.3 - 4.0, in essence, teaching away from using a higher pH for stable hydroquinone compositions."

There is no doubt that the '054 patent discloses (column 7, lines 40-56), a prophylactic and therapeutic composition for treating age spots and keratoses that has a pH of 3.3. This composition, however, contains 2% hydroquinone, 1% malic acid, 19% gluconolactone and 0.5% citric acid. The '054 patent also discloses (column 13, lines 11-21), a therapeutic composition for treating age spots, keratoses, melasmas, lentigines and other pigmented skin spots that has a pH of 4.0. This composition, however, contains 4% hydroquinone, and 12% 2-methyl 2-hydroxypropanoic acid. Contrary to appellants' intimation, we do not find the cited sections of the '054 patent to teach that compositions containing four percent (4%) or less hydroquinone are only stable if they are prepared in a pH range of 3.3 - 4.0. In this regard, we note that the compositions taught by the cited sections of the '054 patent bear little resemblance to the compositions taught by Gordon, or those set forth in appellants' claim 1. Further, we note, in response to appellants' argument, the examiner's cites to Lukenbach, which teaches a composition having a pH of 7.5 that comprises hydroquinone.

Based on evidence of record, we are not persuaded by appellants' assertion (Brief, page 7), "one of ordinary skill in the art would not find it obvious

to prepare a hydroquinone composition at the higher claimed pH because the higher pH would be thought to induce instability and decomposition." In our opinion, the evidence of record does not support this conclusion. Thus, appellants failed to meet their burden under Best, of demonstrating that the compositions taught by Gordon[2] (e.g., those set forth in Table 1, column 2, together with 1.5-4% hydroquinone as set forth on column 2, lines 66-67 as required by Gordon's claim 1) do not necessarily or inherently possess the same pH as appellants' claimed composition.

Accordingly, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as being obvious over Gordon. As set forth above, claims 4-10 and 14-18 fall together with claim 1.

Claim 2:

According to appellants (Brief, page 4), claims 2 and 3 stand or fall together. Accordingly, we limit our discussion to representative claim 2. Claim 3 will stand or fall together with claim 2. Young.

According to appellants (Brief, page 8), Gordon does not teach the pH range recited in claim 2. For clarity, we note that claim 2 depends from and further limits the pH of the composition set forth in appellants' claim 1, from a pH of about 5.5 to about 8.0, to a pH of about 5.5 to about 7.5. As discussed above, there is no evidence on this record that the compositions taught by Gordon do

[2] We note of interest that the assignee of the instant application is the same as that of Gordon. Accordingly, it would appear that appellants would be able to identify the pH of the compositions set forth in Gordon.

not necessarily or inherently possess the same pH as appellants' claimed composition.

Accordingly, for the same reasons as set forth above, we affirm the rejection of claim 2 under 35 U.S.C. § 103(a) as being obvious over Gordon. As set forth above, claim 3 falls together with claim 2.

Claims 11-13 and 19-23:

According to appellants (Brief, page 8), claims 11-13, 19 and 20-23 recite additional limitations which are not taught by Gordon. For clarity, we note that claims 11-13, 19 and 20 ultimately depend from and further limit the composition of claim 1 to include as a further ingredient the water-soluble antioxidant sodium metabisulfite.[3] Claim 21 depends from and further limits claim 1 to a composition "wherein the cationic salt comprises an amino acyl derivative." Claim 22 depends from and further limits the cationic salt of claim 21 to one that "comprises an aminopropyl ascorbyl phosphate." Claim 23 depends from and further limits claim 1 to a composition "wherein the cationic salt comprises a sodium ascorbyl phosphate."

[3] In addition, we note that claims 19 and 20 limit the cationic salt of the composition set forth in claim 1, to one that "comprises magnesium ascorbyl phosphate." However, since appellants do not address this limitation we will not discuss it further.

The examiner recognizes (Answer, page 4), while Gordon teaches a composition that contains, inter alia, sodium bisulfite, and a derivative of ascorbic acid (such as ascorbityl palmitate, magnesium ascorbityl phosphate, and ascorbityl linoleate), Gordon does not teach sodium metabisulfite, aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate. As we understand it, to make up for these deficiencies in Gordon, the examiner asserts (Answer, bridging paragraph, pages 4-5), a person of ordinary skill in the art would have been motivated to modify Gordon's disclosure because sodium bisulfite and the ascorbic acid derivatives disclosed by Gordon share similar chemical structures and properties with the sodium metabisulfite, aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate as recited in appellants' claims.

In support of this assertion, the examiner directs attention to the "extrinsic supporting documents" listed on the PTO-892 form of record in this application. Upon consideration of the electronic file wrapper, we find the PTO-892 entered into the record on April 23, 2003 is the only PTO-892 form of record in this application. The PTO-892 form of record in this application identifies, in addition to Gordon and Lukenbach, four other U.S. Patents: U.S. Patent Nos. 6,417,226, 5,874,463, 6,030,374 and 5,935,556. Upon consideration of these references we find no evidence, and the examiner fails to direct our attention to any specific evidence, that supports her assertion that a person of ordinary skill in this art would found it prima facie obvious to substitute sodium metabisulfite, aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate as recited in

appellants' claims for sodium bisulfite and the ascorbic acid derivatives disclosed by Gordon.

While it is true that an express suggestion to substitute one compound for another equivalent compound need not be present in order to render such a substitution obvious, the prior art must first recognize that the two components are equivalent. In re Fout, 675 F.2d 297, 301, 213 USPQ 532, 536 (CCPA 1982). On this record, however, the examiner failed to direct our attention to any evidence that would suggest that a person of ordinary skill in the art would have considered the sodium bisulfite and ascorbic acid derivatives disclosed by Gordon to be the equivalent of sodium metabisulfite, aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate as recited in appellants' claims.

Since the evidence of record does not support the examiner's assertion, we reverse the rejection of claims 11-13 and 19-23 under 35 U.S.C. § 103(a) as being obvious over Gordon.

The combination of Lukenbach and Gordon:

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Lukenbach and Gordon. Appellants group claims 1 and 4-9 separately from claims 2 and 3. Brief, page 4. However, in response to this ground of rejection, appellants do not provide separate arguments for the two groups of claims. Accordingly, we limit our discussion to representative claim 1. Claims 2-9 will stand or fall together with claim 1.

According to the examiner (Answer, page 5), Lukenbach provides two examples of skin whitening compositions that have a pH of 7.5. In this regard, we note that both skin whitening compositions contain exactly the same ingredients except for the active skin whitening agent. See Lukenbach, column 16, Examples 100B and 100C. The first composition (Example 100B, column 16) comprises the skin whitening agent -magnesium ascorbyl phosphate (a cationic salt of acidic ascorbyl esters). The second composition (Example 100C, column 16) comprises the skin whitening agent - hydroquinone. According to the examiner (Answer, page 5), Lukenbach differs from appellants' claimed composition by not teaching a composition that comprises both magnesium ascorbyl phosphate and hydroquinone. However, as set forth in In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." In support of this proposition, the examiner relies on Gordon to teach a composition that comprises both magnesium ascorbyl phosphate and hydroquinone. Answer, page 5. Based on the foregoing, it is our opinion that the examiner met her burden of presenting a prima facie case of obviousness, and properly shifted the evidentiary burden to appellants. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

In response, appellants rely on two Declarations[4] of Philip J. Gordon[5], which according to appellants provide evidence of unexpected results. According to appellants (Brief, bridging sentence, pages 10-11), "Lukenbach in conjunction with Gordon, fails to teach the cosmetically acceptable combination of the active agents at the given pH, a problem addressed by the present invention." According to the first Declaration (paragraph 2), the compositions set forth in Examples 100B and 100C of Lukenbach were prepared and adjusted to a pH of 7.5. After studying the effect of temperature and time on the compositions, declarant concludes (Declaration, paragraph 8):

> Example 100C ... when prepared in accordance with the instructions provided by the patent, suggests that the hydroquinone rapidly degrades due to the high pH (7.5) of the formula. Example 100C appears to be fluffy and not smooth. Further, Example 100C is not a good cosmetic emulsion due to the color instability after two weeks at 40°C..., further having an initial color of brown, which may be due to hydroquinone degradation.

By way of comparison, appellants' Supplemental Declaration describes the preparation of a composition within the scope of their invention. According to the Supplemental Declaration (paragraph, 2), this composition had a pH of about 5.70-5.80. After studying the effect of temperature and time on the compositions, declarant concludes (Declaration, paragraph 8), the composition "when prepared in accordance with the instructions provided by the application,

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[4] Philip J. Gordon favored this record with two Declarations. The first Declaration was entered into the record on October 23, 2003. Subsequently, a Supplemental Declaration was entered into the record on December 11, 2003.

[5] We recognize appellants' clarification (Brief, page 11, n.1), "Philip J. Gordon, an inventor on the present application, is not Benjamin Gordon from the Gordon reference (U.S. Patent No. 5,932,612) cited by the [e]xaminer."

appears to represent a viable cosmetic formulation due to it not discoloring, indicating a stable formulation...."

Based on this evidence appellants assert (Brief, page 11, emphasis removed), "[o]ne of ordinary skill in the art would not expect the combination of the active agents in these unstable formulations to result in a stable, cosmetically pleasing formulation." Therefore, appellants assert (id.), "as compared to Lukenbach's embodiments, the stability and resulting pleasing aesthetics of the present invention are unexpected in the applicant's [sic] invention and is not rendered obvious by Lukenbach and Gordon."

We note, however, that while appellants prepared the compositions of Lukenbach at a pH of 7.5, they prepared the comparative composition of their claimed invention at a pH of about 5.70-5.80. According to appellants' claim 1, the composition has a pH of about 5.5 to about 8.0. The pH of the compositions disclosed by Lukenbach is within the range recited in appellants' claim 1. Accordingly, it is unclear why appellants elected to compare Lukenbach's compositions, which have a pH of 7.5, to a composition having a pH of about 5.70-5.80. In this regard, we remind appellants that in order to establish unexpected results for a claimed invention, objective evidence of non-obviousness must be commensurate in scope with the claims that the evidence is offered to support. In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978); In re Lindner, 59 CCPA 920, 923, 457 F.2d 506, 508, 173 USPQ 356, 358 (1972); In re Tiffin, 58 CCPA 1420, 1421, 448 F.2d 791, 792, 171 USPQ 294 (1971). On this record, there is no evidence that a composition

having a pH of 7.5 that was prepared according to appellants' disclosure would exhibit a different result than those observed for the compositions taught by Lukenbach. Accordingly, we are not persuaded by appellants' evidence of unexpected results.

Having found appellants' evidence of unexpected results insufficient to overcome the examiner's prima facie case of obviousness, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as being obvious over the combination of Lukenbach and Gordon. As set forth above, claims 2-9 fall together with claim 1.

SUMMARY

The rejection of claims 1-10 and 14-18 under 35 U.S.C. § 103(a) as being obvious over Gordon is affirmed.

The rejection of claims 1-9 under 35 U.S.C. § 103(a) as being obvious over the combination of Lukenbach and Gordon is affirmed.

The rejection of claims 11-13 and 19-23 under 35 U.S.C. § 103(a) as being obvious over Gordon is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Joan Ellis
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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